PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

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DK-1264 Copenhagen K.
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21 JUNI 2004
HØIBERG

PCT

WRITTEN OPINION
(PCT Rule 66)

Date of mailing *(day/month/year)*	17.06.2004
Applicant's or agent's file reference: P715PC00	**REPLY DUE** **within 3 month(s)** from the above date of mailing

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/DK 03/00533	11.08.2003	12.08.2002

International Patent Classification (IPC) or both national classification and IPC
A61M1/00

Applicant
TRACECOMPANY HOLDING APS et al.

1. This written opinion is the **first** drawn up by this International Preliminary Examining Authority.

2. This opinion contains indications relating to the following items:

I	☒	Basis of the opinion
II	☐	Priority
III	☒	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
IV	☒	Lack of unity of invention
V	☐	Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
VI	☐	Certain documents cited
VII	☐	Certain defects in the international application
VIII	☐	Certain observations on the international application

3. The applicant is hereby **invited to reply** to this opinion.

When? See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d).

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also: For an additional opportunity to submit amendments, see Rule 66.4.
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis.
For an informal communication with the examiner, see Rule 66.6.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 12.12.2004

Name and mailing address of the international preliminary examining authority:

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D-80298 Munich
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Authorized Officer
Pille, S

Formalities officer (incl. extension of time limits)
Gamboa Susin, B
Telephone No. +49 89 2399-6086

I. Basis of the opinion

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed")*:

Description, Pages

1-18 as originally filed

Claims, Numbers

1-87 as originally filed

Drawings, Sheets

1/10-10/10 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   - ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
   - ☐ the language of publication of the international application (under Rule 48.3(b)).
   - ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   - ☐ contained in the international application in written form.
   - ☐ filed together with the international application in computer readable form.
   - ☐ furnished subsequently to this Authority in written form.
   - ☐ furnished subsequently to this Authority in computer readable form.
   - ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
   - ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   - ☐ the description, pages:
   - ☐ the claims, Nos.:
   - ☐ the drawings, sheets:

5. ☐ This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been and will not be examined in respect of:

   ☒ the entire international application,

   ☐ claims Nos.

   because:

   ☒ the said international application, or the said claims Nos. 86, 87 relate to the following subject matter which does not require an international preliminary examination (specify):

   see separate sheet

   ☒ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. 1-47, 56-87 are so unclear that no meaningful opinion could be formed *(specify)*:

   see separate sheet

   ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

   ☒ no international search report has been established for the said claims Nos. 48-55

2. A written opinion cannot be drawn due to the failure of the nucleotide and/or amino acid sequence listing to comply with the Standard provided for in Annex C of the Administrative Instructions:

   ☐ the written form has not been furnished or does not comply with the Standard.

   ☐ the computer readable form has not been furnished or does not comply with the Standard.

IV. Lack of unity of invention

1. In response to the invitation (Form PCT/IPEA/405) to restrict or pay additional fees, the applicant has:

   ☐ restricted the claims.

   ☐ paid additional fees.

   ☐ paid additional fees under protest.

   ☐ neither restricted nor paid additional fees.

2. ☒ This Authority found that the requirement of unity of invention is not complied with for the following reasons and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees:

   see separate sheet

3. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this opinion:

   ☐ all parts.

   ☒ the parts relating to claims Nos. 1-47, 56-87 .

ad III

1). Although claims 1, 56 (device claims) and 83, 85, 86 (method claims) have been drafted as separate independent claims, they appear to relate effectively to the same subject-matter and to differ from each other only with regard to the definition of the subject-matter for which protection is sought. The aforementioned claims therefore lack conciseness. Moreover, lack of clarity of the claims as a whole arises, since the plurality of claims makes it difficult, to determine the matter for which protection is sought, and places an undue burden on others seeking to establish the extent of the protection.

Hence, these claims do not meet the requirements of Article 6 PCT.

In order to overcome this objection, it would appear appropriate to file an amended set of claims defining the relevant subject-matter in terms of a single independent claim in each category followed by an appropriate number of dependent claims covering features which are merely optional (Rule 6.4 PCT).

In the present case it is not expedient to give an opinion as to novelty and inventive step on any one of the independent claims as it is not recognisable which independent claim relates to the main invention.

2). Claims 3-13 are unclear as they do not bring forth additional features of the claimed device.

3). For the assessment of the present claims 86 and 87 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. These claims relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT: therapeutic methods. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(I) PCT).

ad IV

4). The application is considered to lack unity for the same reasons as given in the International Search Report.

European Patent Office
D-80298 München
Germany

Att.: S. Pille

September 16, 2004

COPY

Patent Application No. PCT/DK03/00533

TraceCompany Holding Aps
Our ref.: P715PC00

Dear S. Pille,

This is response to the communication dated 17 June 2004. Applicant respectfully requests examiner to issue a second written opinion based on the enclosed new set of claims.

Unity
Previously filed claims 48-55, relating to a container, have been deleted.

Clarity
Summary of changes:

a) Previously filed claim 56 is now present claim 1. Previously filed claims 1 and 14-47 have been amended to become dependent on new claim 1. Previously filed claims 57-82 have been deleted. Previously filed claims 83 and 85 have been amended to be dependent on new claim 37.

There is thus now only one independent claim in each claim category, as follows:

Claims 1-36 are to a device for oral administration of a fluid source to an animal
Claims 37-48 are to a method for oral administration of a fluid or liquid source to an animal
Claims 49-50 are to a method for conferring passive immunity to a newly born domestic animal.

b) Previously filed claims 3-13 have been amended to method claims, dependent on new claim 38.

c) Claim number has been reduced from 87 claims to 50 claims.

Basis for new claim set
New claim 1 has basis in previously filed claim 56.

New claim 2 has basis in previously filed claim 1.

New claim 3 has basis in previously filed claims 14 and 57 and on p11, line 21-23.

New claim 4 has basis on p11, line 26-27.

New claim 5 has basis on p11, line 34 - p12, line 1.

New claim 6 has basis in previously filed claims 17 and 60.

New claim 7 has basis in previously filed claims 18 and 61.

New claim 8 has basis in previously filed claims 19 and 62.

New claim 9 has basis in previously filed claims 20 and 63.

New claim 10 has basis in previously filed claims 21 and 64.

New claim 11 has basis in previously filed claims 22 and 65.

New claim 12 has basis in previously filed claims 23 and 66.

New claim 13 has basis in previously filed claims 24 and 67.

New claim 14 has basis in previously filed claim 25 and p12, lines 28-30.

New claim 15 has basis in previously filed claim 26 and p13, line 17.

New claim 16 has basis in previously filed claims 27 and p12, line 33.

New claim 17 has basis on p13, line 22-23.

New claim 18 has basis on p13, line 22-23.

New claim 19 has basis in previously filed claim claims 30 and 72.

New claim 20 has basis on p14, line 12.

New claim 21 has basis in previously filed claims 32 and 74.

New claim 22 has basis in previously filed claims 33 and 75.

New claim 23 has basis in previously filed claim 34 and 76.

New claim 24 has basis in previously filed claim 35 and 77.

New claim 25 has basis in previously filed claims 36 and 78.

New claim 26 has basis in previously filed claims 37 and 79.

New claim 27 has basis in previously filed claims 38 and 80.

New claim 28 has basis on p15, line 22-24.

New claim 29 has basis in previously filed claims 40 and 82.

New claim 30 has basis in previously filed claim 41.

New claim 31 has basis in previously filed claim 42.

New claim 32 has basis in previously filed claim 43.

New claim 33 has basis in previously filed claim 44.

New claim 34 has basis in previously filed claim 45.

New claim 35 has basis in previously filed claim 46.

New claim 36 has basis in previously filed claim 47.

New claim 37 has basis on p6, lines 17-28.

New claim 38 has basis in previously filed claim 83.

New claim 39 has basis in previously filed claim 84.

New claim 40 has basis on p3, line 32 and p18, line 20-21.

New claim 41 has basis on p3, lines 32-33, and p18, line 20-21

New claim 42 has basis on p18, line 20-21.

New claim 43 has basis on p18, line 20-21.

New claim 44 has basis on p10, lines 18-19.

New claim 45 has basis in previously filed claim 10, which has been re-drafted as a method claim.

New claim 46 has basis in previously filed claim 11, which has been re-drafted as a method claim.

New claim 47 has basis in previously filed claim 12, which has been re-drafted as a method claim.

New claim 48 has basis in previously filed claim 13, which has been re-drafted as a method claim.

New claim 49 has basis on p7, line 10-21.

New claim 50 has basis in previously filed claim 87.

Yours sincerely,
HØIBERG A/S

Susanne Høiberg

Claims

1. A device for oral administration of a fluid source to an animal, said device comprising

   i) a hollow, axially-elongated member comprising
      a) a distal end comprising a first opening, preferably in the form of a nozzle portion, and
      b) a proximal end comprising a second opening connected to

   ii) a handle comprising
      a) a distal portion connecting the handle to said axially-elongated member, and
      b) a proximal portion connecting the handle to

   iii) a flexible tube comprising
      c) a distal end comprising a first opening connected to the handle, and
      d) a proximal end comprising a second opening connected to

   iv) a hollow adaptor capable of attaching the flexible tube to a fluid source container, said adaptor comprising
      a) a distal end comprising a first opening, said distal end capable of securing attachment of said adaptor to the tubing, and
      b) a proximal end comprising a second opening, said proximal end capable of bringing the adaptor in contact with the fluid source stored in

   v) said device further comprising a switch mechanism for regulating the flow of liquid through the axially-elongated member.

2. The device according to claim 1, wherein said device is portable, and wherein the fluid source of the device is stored in a container insert,

preferably in the form of a disposable, flexible polymer bag, said container insert being arranged in

a fluid source container fitted to holding said container insert, said fluid source container comprising

a) at least one attachment site capable of securing the attachment of the container to the adaptor, and optionally
b) means for transporting the device by the operator

3. The device according to any of the preceding claims, wherein the axially-elongated member comprising the nozzle portion is capable of being inserted into the esophagus of a domestic animal.

4. The device according to any of the preceding claims, wherein the nozzle is rounded in shape and has an outer diameter larger than the outer diameter of the rest of the axially-elongated member.

5. The device according to any of claims 3 and 4, wherein the nozzle portion is of a shape and size which preferably inhibits the axially-elongated member from being inserted into the trachea of the domestic animal.

6. The device according to any of claims 4-6, wherein said axially-elongated member and said nozzle portion is manufactured as integrated into one piece of material.

7. The device according any of the preceding claims, wherein the axially-elongated member has retained at least some degree of flexibility.

8. The device according to any of claims 1-6, wherein the axially-elongated member is essentially inflexible.

9. The device according to any of the preceding claims, wherein the axially-elongated member comprises or consists of a polymer.

10. The device according to claim 9, wherein the polymer is a thermoplastic polymer.

11. The device according to claim 10, wherein the polymer is polypropylene or polyethylene.

12. The device according to any of the preceding claims, wherein the length of the axially-elongated member from the tip of the nozzle portion to the distal portion of the handle is from 30 cm to 34 cm, such as about 32 cm.

13. The device according to any of the preceding claims, wherein the inner diameter of the axially-elongated member excluding the nozzle portion is from 0.5 cm to 2 cm, such as about 0.8 cm, for example about 1.0 cm, such as about 1.2 cm, for example 1.5 cm.

14. The device according to claim 13, wherein the outer diameter of the axially-elongated member excluding the nozzle portion is from 0.2 cm to about 1 cm larger than the inner diameter of the rest of the axially-elongated member.

15. The device according to any of the preceding claims, wherein the switch mechanism for regulating the flow of fluid source through the axially-elongated member is comprised in the handle.

16. The device according to claim 15, wherein the switch mechanism is manually operated.

17. The device according to any of the preceding claims, wherein the switch mechanism comprises a valve.

18. The device according to any of the preceding claims, wherein the switch mechanism comprise a sliding valve.

19. The device according to any of the preceding claims, wherein the shape and size of the handle prevents it from being inserted into the mouth of the animal thereby preventing the axially-elongated member from reaching

beyond a predetermined region of the esophagus.

20. The device according to any of the preceding claims, wherein the handle is hollow.

21. The device according to any of the preceding claims, wherein the handle is detachably connected to the axially-elongated member.

22. The device according to any of the preceding claims, wherein the handle consists of at least two detachable parts.

23. The device according to any of the preceding claims, wherein the adaptor comprises a tapering end.

24. The device according to claim 23, wherein the tapering end is capable of penetrating said container insert.

25. The device according to claim 24, wherein said adaptor further comprises a shoulder distal to said tapering end for providing a tight connection between the adaptor and said container insert.

26. The device according to any of claims 23 to 25, wherein said adaptor further comprises a plurality of locking pins for securing the attachment of the adaptor to said fluid source container.

27. The device according to any of claims 23 to 26, wherein said adaptor further comprises two oppositely located planar flanges for rotating the adaptor into locking position once it has made contact with the fluid source container.

28. The device according to any of the preceding claims, wherein said adaptor further comprises a portion for detachably connecting the adaptor to a cleaning device.

29. The device according to claim 28, wherein said cleaning device is a water tap optionally fitted with a hosepipe adaptor capable of detachably connecting the water tap to the adaptor of the device.

30. The device according to any of claims 2-29, wherein said container comprises at least one attachment site for the adaptor of the device.

31. The device according to claims 30, wherein said container further comprises means for engagement of said adaptor on the inside of said at least one attachment site.

32. The device according to any of claims 2-31, wherein said container further comprises one or more means for transporting the device by the operator.

33. The device according to claim 32, wherein said means for transporting enable the operator to carry the container on his back.

34. The device according to any of claims 2-33, wherein the container comprises a single polymer sheet capable of folding into a container, said polymer sheet comprising

a first wall portion, a second wall portion, and a base portion

wherein the first wall portion is permanently fixed to said second wall portion along a single first axis,

wherein said first wall portion is permanently fixed to a base portion along a single second axis,

wherein said second wall portion is detachably fixed to said first wall portion along a single third axis,

and wherein said second axis connects said first and third axes.

35. The device according to any of claims 2-34, wherein said container is capable of being unfolded into an essentially planar sheet when not in use.

36. The device according to any of claims 2-35, wherein the container insert is disposable.

37. A method for oral administration of a fluid or liquid source to an animal, said method comprising the steps of

i) providing a fluid or liquid source,

ii) providing a device according to any of the previous claims

iii) filling said container insert of the device with said fluid or liquid source, and

iv) administering said fluid or liquid source to said animal, optionally by operating said switch mechanism.

38. The method according to claim 37, wherein said device is according to any of claims 2-36.

39. The method according to claim 38, wherein the liquid source is selected from the group consisting of colostrum, aqueous solutions of nutrients or electrolytes, aqueous solutions of medicaments and the like.

40. The method according to claim 39, wherein the liquid source is colostrum.

41. The method according to claim 40, wherein the colostrum is obtained from a domestic animal, including a bovine species.

42. The method according to claim 41, wherein the domestic animal is a ruminant.

43. The method according to claim 42, wherein the ruminant is a bovine species.

44. The method according to claim 43, wherein the bovine species is selected from the group consisting of Holstein and Jersey.

45. The method according to any of claims 43 or 44, wherein the bovine species is a newly born bovine species less than twenty days old.

46. The method according to claim 45, wherein the bovine species is a newly born bovine species less than fifteen days old.

47. The method according to claim 46, wherein the bovine species is a newly born bovine species less than ten days old.

48. The method according to claim 47, wherein the bovine species is a newborn bovine species less than five days old.

49. A method for conferring passive immunity to a newly born domestic animal, said method comprising the steps of

i) providing a passive immunity source, such as immunoglobulins,

ii) providing a device according to any of claims 1 to 36,

iii) filling said container insert of the device with said passive immunity source, and

iv) administering said passive immunity source to said bovine species, optionally by operating said switch mechanism.

50. The method of any of claims 38 to 49, wherein the device used is according to any of claims 2-36, and wherein the size of the nozzle allows the operator of the device to determine the present position of the nozzle in the esophagus from the outside of the animal by pressing said nozzle portion against the inside wall of the esophagus.

Nr

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COPY

Att.: S. Pille (Telefax no. +49 89 2399 7422)

9 November 2004

Patent Application No. PCT/DK03/00533
TraceCompany Holding Aps
Our ref.: P715PC00

Dear S. Pille,

This is response to the informal communication having taken place earlier today in the above captioned case. An amended set of claims (1 to 48) is enclosed. Issuance of a rectified IPER is respectfully requested.

Basis for the amended claims

New claim 1 now incorporates claims 1 and 2 filed with our response dated 16 September 2004. Claim 30 is deleted as it cites the feature of an attachment site also cited in claim 2.

The remaining claims have been renumbered accordingly. A basis for the claims is listed in our response dated 16 September 2004.

Novelty

One difference between the present invention and US 5,188,610 can now be found in amended claim 1 (enclosed herewith) citing a "container insert" for storage of the fouid source. The container insert is arranged in the fluid source container. This is illustrated e.g. in Fig. 10 (reference numeral 28). Accordingly, whereas US 5,188,610 operates with a flexible container (12) mounted on a backpack (26), the present invention invention uses a) a container body for containing b) a container insert (flexible polymer bag) for storing the fluid source.

In the present invention the adaptor is connected with the fluid source in the container insert through an opening in the container body. The adaptor is thus "fixed" to the container and penetrates the container insert. This is different from US 5,188,610 in which the connection is made directly to the fluid bag "container" through the port 16.

It is submitted that claim 2 is novel over US 5,188,610.

As neither US 3,774,608 nor GB 727 959 discloses a device according to the present invention comprising a container body and a container insert, the present invention is also novel over US 3,774,608 and GB 727 959.

Inventive step

US 5,188,610 discloses a device which needs for its proper operation both a neck member (36), an adapter (56) and a connector (72). The present invention is more simple and requires only a single adapter.

US 5,188,610 operates with e.g. an IV (intravenous) fluid bag (see column 2, line 48) fitted with a port (16). Such fluid bags are expensive to manufacture. The present invention operates with a simple and inexpensive polymer bag.

The container according to the present invention protects the container insert from sharp objects which could penetrate the unprotected fluid bag of the device of US 5,188,610.

The technical problem to be solved is how to provide a simple device for oral administration of a fluid source to an animal. Starting at US 5,188,610 as the closest prior art, the technical problem has been solved by simplifying the adapter (one piece only) and by fixing the simplified adaptor to a container body rather than fixing the adapter directly onto a port opening of a container insert in the form of a flexible fluid bag.

Nowhere does the prior art disclose this solution to the above technical problem. An inventive step should be acknowledged.

Yours sincerely,
HØIBERG A/S

Jesper Levin Aamand

Amended set of claims (1 to 48)